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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,867	08/21/2001	Chaya Moroz	MOROZ3	6095

1444 7590 04/03/2006

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WASHINGTON, DC 20001-5303

EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,867	MOROZ, CHAYA	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005 and 12 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/20/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Exhibit D

DETAILED ACTION

Claims 67-82 are pending and under consideration.

Sequence Rules

The objection is withdrawn because applicant's statement about pages 15, 19, and 27, Fig. 1-5, and 7 of the specification is correct. New sequence listing, the corresponding CRF, and a new statement have been entered.

Drawings, Objected

The drawings were received on 10/20/2005. These drawings are not acceptable because the three letter codons CAA, and TAT (note the previously provided Exhibit B, mailed on 4/20/2005) are not correct. See also Exhibit D, attached with this Office action. 3-31-06

Information Disclosure Statement

The signed 1449 is attached with this Office action.

Specification, Maintained

The amendment filed 01/31/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The Oath and Declaration filed on 03/21/2001 declares that the instant application is a 371 filed as PCT/IL 99/00485. However, SEQ ID NO:5 filed on 02/04/2005 and SEQ ID NO:5 disclosed in PCT/IL 99/00485 are not identical. Note previously provided Exhibit A (sequence alignment of SEQ ID NO:5 filed on 02/04/2005 and SEQ ID NO:5 disclosed in PCT/IL 99/00485).

Applicant argues that the amendment submitted on August 21, 2001 solved the problem, especially at page 7. However, applicant has not fixed all of the sequence problems. Note the previously Exhibit B, which shows that SEQ ID NO: 5 and SEQ ID NO: 1 do not match, which indicates that there are still problems of translating the nucleic acid sequence to correct protein sequences.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections, Maintained

Claims 70, 77, 79, and 80 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 70 and 77 depend on claims 69, and 76 respectively, which in turn depend on claim 67, and 74 respectively. Claims 70, and 77 say that nucleotides 459-602 of SEQ ID NO:1 encode amino acid residues of 118-165 of SEQ ID NO: 5. However, the sequence alignment of SEQ ID NO: 5 with SEQ ID NO:1 (note Exhibit B) indicate that nucleotides 459-602 of SEQ ID NO:1 do not encode amino acid residues of 118-165 of SEQ ID NO: 5.

Applicant argues that the earlier amendment filed on August 21, 2001 corrected the sequence typographical errors of SEQ ID NO: 5, based nucleic acid sequence as support. However, the previous amendment and the amendment filed on October 20, 2005 has not corrected all the errors raised in the previous Office action. Compare the

previously provided Exhibit B along with the sequence listing submitted on October 20, 2005, especially page 3 of the sequence listing. See attached Exhibit D.

The objection of claims 79, and 80 due to the transitional phrase "consisting of", is withdrawn.

Claim Rejections - 35 USC § 112

Claims 67-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has two parts.

First, claims 68-73 are drawn to genus of products (proteins, nucleic acids, expression vectors, and hosts cells), and method of using said genus of products.

Applicant states that it is not clear why claims 74-82, which uses the transitional phrase "consisting of" were included in this written description rejection. Claims 74-82 are rejected for a new matter. SEQ ID NO:5 is a new matter. See previously provided Exhibits A and B, along with the attached Exhibit D.

As to claim 67-73, applicant argues the specification discloses C48 as well as the entire OFF1, which C48 is a part of OFF1. Thus it is expected that other fragments of OFF1 will have the same activity as has been shown in the present specification for C48.

These arguments have been fully considered but found unpersuasive because applicant argues limitations not present in the claims. The claims do not say any

activity, OFF1, or C48. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial sequence of residues of 118 to 165 of SEQ ID NO: 5. There is not even identification of any particular function associated with the partial sequence. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Applicant also argues that SEQ ID NO: 5 has support. However, the previously provided Exhibits A and B show that 3 amino acids in SEQ ID NO: 5 and the sequence disclosed in PCT/IL 99/00485 are different. Applicant corrected two amino acids, not the third one. See Exhibit D.

The new matter rejection due to '"arthritis" and "rheumatoid arthritis" is withdrawn because applicant's statement is correct. Any other rejection not repeated here is also withdrawn.

The rejection of claims 67-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** because applicant arguments are persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642

ctaattggaa gcgccaccct agcaatatca accattaacc ttccctctac acttatcatc 780

ttcacaattc taattctact gactatccta gaaatcgctg tcgccttaat ccaagcctac 840

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<210> 5
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<212> PRT
<213> Homo sapiens

<400> 5

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1 5 10 15

Ser Glu Ala Ala Ile Asn Arg Gln Ile Asn Leu Glu Leu Tyr Ala Ser
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Tyr Val Tyr Leu Ser Met Ser Tyr Tyr Phe Asp Arg Asp Asp Val Ala
35 40 45

Leu Lys Asn Phe Ala Lys Tyr Phe Leu His Gln Ser His Glu Glu Arg
50 55 60

Glu His Ala Glu Lys Leu Met Lys Leu Gln Asn Gln Arg Gly Gly Arg
65 70 75 80

Ile Phe Leu Gln Asp Ile Lys Lys Pro Asp Cys Asp Asp Trp Glu Ser
85 90 95

Gly Leu Asn Ala Met Glu Cys Ala Leu His Leu Glu Lys Asn Val Asn
100 105 110

Gln Ser Leu Leu Glu Phe Pro Ser Pro Ile Ser Pro Ser Pro Ser Cys
115 120 125

Trp His His Tyr Thr Thr Asn Arg Pro Gln Pro Gln His His Leu Leu
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Arg Pro Arg Arg Arg Lys Arg Pro His Ser Ile Pro Thr Pro Ile Leu
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Ile Phe Arg Ser Pro
165

<210> 6
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<212> DNA
<213> Homo sapiens

<400> 6
ggtggcgacg actcctggag cccg 24

Exhibit D
Page 2 of 2

7/15

TTGACACCAGACCAACTGGTAATGGTAGCGACCGGCGCTCAGCTGGAATTCCGAAAAATGT

AATGCACACTCCATTGCATTCAGCCCGCCTCTCCTTAGTCGCCGCC

met	thr	thr	ala	ser	thr	ser	gln	val	arg	gln
ATG	ACG	ACC	GCG	TCC	ACC	TCG	CAG	GTG	CGC	CAG
asn	tyr	his	gln	asp	ser	glu	ala	ala	ile	asn
AAC	TAC	CAC	CAG	GAC	TCA	GAG	GCC	GCC	ATC	AAC
arg	gln	ile	asn	leu	glu	leu	tyr	ala	ser	tyr
CGC	CAG	ATC	AAC	CTG	GAG	CTC	TAC	GCC	TCC	TAC
val	tyr	leu	ser	met	ser	tyr	tyr	phe	asp	arg
GTT	TAC	CTG	TCC	ATG	TCT	TAC	TAC	TTT	GAC	CGC
asp	asp	val	ala	leu	lys	asn	phe	ala	lys	tyr
GAT	GAT	GTG	GCT	TTG	AAG	AAC	TTT	GCC	AAA	TAC
phe	leu	his	gln	ser	his	glu	glu	arg	glu	his
TTT	CTT	CAC	CAA	TCT	CAT	GAG	GAG	AGG	GAA	CAT
ala	glu	lys	leu	met	lys	leu	gln	asn	gln	arg
GCT	GAG	AAA	CTG	ATG	AAG	CTG	CAG	AAC	CAA	CGA
gly	gly	arg	ile	phe	leu	gln	asp	ile	lys	lys
GGT	GGC	CGA	ATC	TTC	CTT	CAG	GAT	ATC	AAG	AAA
pro	asp	cys	asp	asp	trp	glu	ser	gly	leu	asn
CCA	GAC	TGT	GAT	GAC	TGG	GAG	AGC	GGG	CTG	AAT
ala	met	glu	cys	ala	leu	his	leu	glu	lys	asn
GCA	ATG	GAG	TGT	GCA	TTA	CAT	TTG	GAA	AAA	AAT
val	asn	gln	ser	leu	leu	glu	phe	pro	ser	pro
GTG	AAT	CAG	TCA	CTA	CTG	GAA	TTC	CCT	TCT	CCT
ile	ser	pro	ser	pro	ser	cys	trp	his	his	thr
ATC	TCT	CCC	AGT	CCT	AGC	TGC	TGG	CAT	CAC	TAT
thr	thr	asn	arg	pro	glu	pro	gln	his	his	leu
ACT	ACT	AAC	AGA	CCG	CAA	CCT	CAA	CAC	CAC	CTT
leu	arg	pro	arg	arg	arg	lys	arg	pro	his	ser
CTT	CGA	CCC	CGC	CGG	AGG	AAG	AGA	CCC	CAT	TCT
ile	pro	thr	pro	ile	leu	ile	phe	arg	ser	pro
ATA	CCA	ACA	CCT	ATT	CTG	ATT	TTT	CGG	TCA	CCC

TGA AGTTTATATTCTTATCCTACCAGGCTTCGGAATAATCTCCCATATTGTAACTTAC

TACTCCGGAAATCGCTGTCGCCTAACCGCTAACATTACTGCAGGCCACCTACTCATGCAC

CTAATTGGAAGCGCCACCCTAGCAATATCAACCATTAACCTTCCCTCTACACTTATCATC

TTCACAATTCTAATTCTACTGACTATCCTAGAAATCGCTGTCGCCTTAATCCAAGCCTAC

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Fig. 5